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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,752	06/26/2003	Alain Delcayre	11000.1042c3	6415

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EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,752	DELCAYRE, ALAIN	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date: _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending in this application and subject to restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 9, 10, 12, 14 and 15, drawn to a polypeptide comprising an amino acid selected from the group consisting SEQ ID NOs: 61-77, classified in class 530, subclass 350.

II. Claims 3-8, 11, 13 and 16, drawn to a polynucleotide comprising a nucleic acid selected from the group consisting of SEQ ID NOs: 8-21, classified in class 435, subclass 320.1.

III. Claims 17-21, drawn to a method for enhancing an immune response in a patient comprising administering a composition of Group I, classified in class 514, subclass 2 and class 424, subclass 168.1.

IV. Claims 17-21, drawn to a method for enhancing an immune response in a patient comprising administering a composition of Group II, classified in class 514, subclass 44 and class 424, subclass 168.1.

V. Claim 22, drawn to a method for the treatment of an immune disorder comprising administering a composition of Group I, classified in class 514, subclass 2.

VI. Claim 22, drawn to a method for the treatment of an immune disorder comprising administering a composition of Group I, classified in class 514, subclass 44.

VII. Claims 22-23, drawn to a method for the treatment of an infectious disease comprising administering a composition of Group I, classified in class 514, subclass 2.

VIII. Claims 22-23, drawn to a method for the treatment of an infectious disease comprising administering a composition of Group I, classified in class 514, subclass 44.

IX. Claims 22, drawn to a method for the treatment of cancer comprising administering a composition of Group I, classified in class 514, subclass 2.

X. Claims 22, drawn to a method for the treatment of cancer comprising administering a composition of Group II, classified in class 514, subclass 44.

The inventions are distinct each from the other because of the following reasons:

Groups I, III, V, VII and X read on sequences selected from the group comprising one of unrelated SEQ ID NO:s 61-77. As well, these groups comprises a fusion protein of which the sequence further comprises one of the sequences selected form the group comprising of SEQ ID NO:s 79-81, 90-97 and 116. Each sequence is patentably distinct because they are unrelated sequences, encoding distinct polypeptides. Should applicants select Group I, applicants must elect a single sequence for examination as regards the sequence from SEQ ID NO:s 61-77 and a single sequence from SEQ ID NO:s 79-81, 90-97 and 116.

Group II, IV, VI, VIII and X read on a polynucleotide selected from a group of 9 patentably distinct polynucleotide sequences comprising one of unrelated SEQ ID NO:s: 8-21. As well, these groups comprises one of the sequences selected form the group comprising of SEQ ID NO:s 56-58 and 82-89. Each sequence is patentably distinct because they are unrelated sequences, encoding distinct polynucleotides. Should applicants select Group II, applicants must elect a single sequence for examination as regards the sequence from SEQ ID NO:s 8-21and a single sequence from SEQ ID NO:s 56-58 and 82-89.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, select to a restriction requirements pursuant to 35 U.S.C. 1121 and CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry to protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

It has been decided that, due to the high burden placed on the Office to search sequences, ONE sequence constitutes a reasonable number for examination purposes. Applicant is required to elect ONE independent and distinct sequence. Examination will be restricted to only the one elected sequence. The search of no more than one selected sequences may include the complements of the selected sequence and where appropriate,

may include subsequences within the selected sequence (i.e. oligomeric probes and/or primers).

The polypeptide of Group I and polynucleotide of Group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. A polypeptide of group I can made by methods using some, but not all, of the polynucleotides that fall within the scope of Group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of Groups I and II are patentably distinct.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not

coextensive. As such, it would be burdensome to search the inventions of groups I and II together.

Inventions III-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method for enhancing an immune response in a patient comprising administering a composition of Group I (Group III), the a method for enhancing an immune response in a patient comprising administering a composition of Group II (Group IV), the method of treatment of an immune disorder comprising administering a composition of Group I (Group V), the method of treatment of an immune disorder comprising administering a composition of Group II (Group VI), the method for the treatment of an infectious disease comprising administering a composition of Group I (Group VII), the method for the treatment of an infectious disease comprising administering a composition of Group II (Group VIII), the method for the treatment of cancer comprising administering a composition of Group I (Group IX) and the method for the treatment of cancer comprising administering a composition of Group II (Group X) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for each method differs significantly. For administration of a polypeptide (Groups III, V, VII and IX), the methods and materials differ from methods of administration of a polynucleotide (Groups IV, VI, VIII and X). Furthermore,

methods and material for related to enhancing immune responses and treating immune disorders, infectious disease and cancer have different purpose, different method steps and different technical consideration. For example, methods of enhancing an immune response will not necessarily led to treatment of infectious disease, immune disorders or cancer and the compositions required for enhancing an immune response are not necessarily the same as those required to treat an immune disorder or treat an infectious disease or treat cancer. Target subjects of each will necessarily differ as well as consideration of specific antigens to be injected. Thus, each of the antigens differ in properties and compositions. Therefore, each method is divergent in materials and steps. For these reasons the Inventions III-X are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches as they are not coextensive. A search for art pertaining to methods of enhancing immune responses is not coextensive with methods for treating disorders and diseases and cancer. Furthermore, a method of treatment of immune disorders, infectious disease and cancer are not coextensive. As such, it would be burdensome to search the inventions of Groups III-X together.

Inventions I and either III, V, VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group I can be use to can be used to generate antibodies for detection of diseases.

Searching the inventions of Groups I and either III, V, VII and IX together would impose serious search burden. The inventions of Groups I and either III, V, VII and IX have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of treatment using the polypeptide are not coextensive. Group I encompasses molecules which are claimed in regard to reference sequence SEQ ID NO:s, which are not required for the search of Group III, V and VII. In contrast, the search for Group III, V, VII and IX would require a text search for the methods in addition to a sequence search. Prior art, which teaches a polypeptide that is SEQ ID NO:s 61-77 would not necessarily be applicable to the method of using the SEQ ID NO:s. Moreover, even if the polypeptide were known, the method of treatment using the product may be novel and unobvious in view of the preamble or active steps.

Inventions II and IV, VI, VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of group II can be use in methods of identifying related sequences.

Searching the inventions of Groups II and either IV, VI, VIII and X together would impose serious search burden. The inventions of Groups II and either IV, VI, VIII and X have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and method of treatment

using a polynucleotide are not coextensive. Group I encompasses molecules which are claimed in regard to reference sequence SEQ ID NO:s, which are not required for the search of Group III-IV. In contrast, the search for group IV, VI, VIII and X would require a text search for the methods in addition to a search of SEQ ID NO:s 8-21. Prior art, which teaches a polynucleotide that is SEQ ID NO:s 8-21 would not necessarily be applicable to the method of using the SEQ ID NO:s. Moreover, even if the polynucleotide product were known, the method of diagnosis using the product may be novel and unobvious in view of the preamble or active steps.

Inventions of Group I and III, V, VII and IX are unrelated because the product of Group II is not used or otherwise involved in the process of group III, V, VII and IX.

Inventions of Group II and either IV, VI, VIII and X are unrelated because the product of Group II is not used or otherwise involved in the process of group IV, VI, VIII and X.

Claim 22 links the inventions of Groups V-X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claim depending from or including all the limitations of the allowable linking claims is presented in the continuation or divisional application, the claims of the continuation of divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See MPEP 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer* and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

June 28, 2005

Daniel M. Sullivan
Patent Examiner